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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/911,824 08/15/97 HACKETT, JR.

J 6165.US.01

023492 HM12/0131  
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DEPT. 377 - AP6D-2  
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EXAMINER

NELSON, B

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

01/31/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/911,824

Applicant(s)  
Hackett et al.

Examiner  
Brett Nelson

Group Art Unit  
1648



☒ Responsive to communication(s) filed on Dec. 4, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1 and 2 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 1 is/are allowed.

☒ Claim(s) 2 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4-6, 9

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1648

### DETAILED ACTION

1. The examiner acknowledges the receipt of applicant's Election of Group 1, claims 1 and 2 and deleting claims 3-77. Therefore, claims 1 and 2 are pending and under consideration.

#### *Claim Rejections - 35 USC § 112*

2. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, based upon the revised Interim Written Description guidelines published in the Federal Register on December 21, 1999, (and 1231 OG 123, February 29, 2000) and on the associated training materials which are available on the Internet at:

<http://www.uspto.gov/web/offices/pac/writtendesc.pdf>

Claim 2 are drawn to any HIV-1 Group O env polypeptides that contain an immunoreactive portion of SEQ ID NO: 61. A review of the language of the claim indicates that the claim is drawn to a genus. While the specification discloses immunoreactive portions of one specie of HIV-1 Group O env, it does not disclose the entire species which is encompassed in the claim.

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The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses all HIV-1 Group O env polypeptide which are not further described. There is substantial variability among the species of HIV-1 Group O encompassed within the scope of the claims. When reviewing a claim that encompasses a widely varying genus, the examiner must evaluate any necessary common attributes or features. In the case of a polypeptide that is claimed with open language (comprising), the genus of, e.g., "A polypeptide comprising [a immunoreactive portion of one genus]," encompasses a variety of subgenera with widely varying attributes. Defining "the" polypeptide in functional terms would not suffice in the absence of a disclosure of structural features or elements of other polypeptides having a stated function.

A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Here, the specification discloses only a single specie. Since the claimed genus encompasses polypeptides yet to be discovered the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of SEQ ID NO:61 does not provide an adequate description of the claimed genus "comprising" these sequences or comprising an immunoreactive portion of SEQ ID NO: 61.

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Weighing all factors, 1) structure of the polypeptides that comprise the recited immunoreactive portions of SEQ ID No. 61, 2) the breadth of the claim as reading on polypeptides yet to be discovered, 3) the lack of correlation between the structure and the function of the polypeptides; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of HIV-1 Group O env polypeptides that have an immunoreactive portion of one SEQ ID No.:

Therefore, in view of the above, it is determined that the specification lacks adequate written description for the claimed invention.

3. Claim 1 appears allowable.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brett Nelson, Art Unit 1648 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number is (703)308-4426. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Brett Nelson whose telephone number is (703) 306-3219.

If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner James C. Housel whose telephone number is (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NELSON/bn  
January 31, 2001

  
BRETT L. NELSON  
PATENT EXAMINER